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RISK CHARACTERIZATION

In the **Risk Characterization** phase the results of the exposure and ecological effects analyses are used to evaluate the likelihood of adverse effects occurring. Risk characterization includes a summary of the assumptions used, the scientific uncertainties, and the strengths and weaknesses of the analyses. Also, the ecological significance of the risks is discussed, with consideration of the types and magnitudes of the effects, their spatial and temporal patterns, and the likelihood of recovery.

Table of Contents for the Risk Characterization Phase

Risk Estimation

Risk to Individuals

The risks to the survival and reproduction of individual birds will be qualitatively estimated from several lines of evidence, including the general toxicity of chlorfenapyr to birds, the general partitioning and degradation of chlorfenapyr in the environment, bird species using cotton, timing of applications of chlorfenapyr, biomass of avian food in treated fields, avian field study results, and ancillary Section 18 monitoring results. Each of these lines of evidence has been developed in detail in the Analysis, and will be considered in turn.

Chlorfenapyr is highly or very highly toxic by the oral route of exposure to upland game birds, waterfowl, and songbirds in laboratory studies. It is reasonable to expect that these characteristics will hold true for most, if not all, species of birds. A theoretical analysis of the potential partitioning of chlorfenapyr into environmental compartments after application, supported by data from laboratory and field information, indicates that ingestion is the most significant route of exposure.

After chlorfenapyr is applied, residues may be present at some level in weed seeds, insects, and fruits. Residue levels of chlorfenapyr from weed seeds, insects, and fruits on the treated cotton field have been shown to be much higher than residues on these items in the borders of the cotton agroenvironment. This is consistent with available information concerning drift. Some chlorfenapyr may also reach the soil surface. The compound is not persistent in weed seeds, insects, and fruits. It is more persistent in soil, but a theoretical worst-case analysis based on chlorfenapyr's physical and chemical characteristics and the Universal Soil Loss Equation showed that residues would not accumulate to harmful levels even if birds' diets were assumed to consist of 100% soil. Physical and chemical characteristics of chlorfenapyr and information from the literature indicates that bound residues are not expected to be bioavailable from soil. Concentrations in sediments have been estimated with modeling techniques; exposures were shown to be insignificant.

The bird species using cotton have been identified and the diets of the most commonly observed birds include weed seeds, insects, and fruits. The critical variable affecting exposure will be the degree to which birds forage in the cotton agroenvironment. Censuses and field studies have shown that bird usage of cotton fields themselves is low; at present a quantitative estimate has not been made definitively, but less than 50% of the time is a reasonable but conservative working estimate.

Southern Cotton

In Southern Cotton, chlorfenapyr will primarily be applied from July through September. At that time, the bird species associated with the cotton agroenvironment will generally have completed, or be near completion of, their breeding seasons (See Appendix 5). For this reason, effects on reproduction are not expected, because birds will have minimal exposure to residues of chlorfenapyr during the breeding season.

During the interval from July through September, insect biomass in cotton is generally decreasing, even in unmanaged fields. We have shown that in managed fields, treatment at the economic threshold levels will result in low biomass of insects per acre. Information about the available biomass in cotton fields compared to adjacent habitats (e.g., soybeans) provides a plausible explanation for the low usage of cotton fields by birds observed in censuses. Weed control minimizes the standing crop of weeds in cotton fields, and few fruits are expected to be growing in the fields, also consistent with low bird usage. If one considers that the caloric requirements of birds actively feeding young will be even greater than their maintenance requirements, then the suitability of cotton fields for foraging birds is reduced even more.

A field study in Louisiana showed that a single application of chlorfenapyr at 0.35 lb. a.i./A had no apparent effects on avian species abundance or diversity. Sensitive telemetry testing showed that there were no differences in survivorship of birds on treated and reference fields. These results are in agreement with the expected low degree of usage of cotton fields by birds. Monitoring efforts for Section 18 Emergency Exemptions (MRID No. 43887001), while not highly sensitive, did not find mortality after applications of chlorfenapyr under commercial conditions and should be given some consideration as ancillary evidence.

Taken together, the above lines of evidence indicate that use of chlorfenapyr poses a low or very low risk to survival or reproduction of individual birds in Southern Cotton.

Western Cotton

Much of the information presented above for Southern Cotton also applies to Western Cotton. General toxicity and general partitioning in the environment will be similar. There will be differences in bird species, but the most common species using Western Cotton agroenvironments have been shown to eat insects, weed seeds, or fruits.

A significant difference between the timing of use in Western Cotton and in Southern Cotton is the applications for mite control made in Western Cotton. These applications are made early in the season, when cotton plants are about one foot tall. Although the application rate is low, at most 0.15 lb. a.i./A, these treatments are made during the time many species of birds are breeding. Later applications for worm control in Western Cotton, although at higher use rates, will occur when most, if not all, species have completed or are near completing their breeding.

With regard to the early season application, we have shown that bird usage of Western Cotton at this time was generally low; fields were infrequently visited by birds (see avian census and Arizona pilot study results). The amount of food available will be very limited since weeds would be controlled at this time and little cover would be present for colonization by insects. Recall from the discussion of biomass (see Ecosystem and Receptor Characteristics – Biotic Factors - Insects in Cotton as an Avian Food Source, page 53 and Appendix 7) that biomass levels are very low in cotton fields during the early season. If one considers that the caloric requirements of birds actively feeding young will be even greater than their maintenance requirements, then the suitability of cotton fields for foraging birds is even less. Also, the applications for the early season control of mites would be entirely by ground. This would greatly limit the potential for off-site movement of chlorfenapyr. The birds that may be at greatest risk of exposure would be open habitat or bare-ground nesting species, such as Horned Larks, that may find the open canopy of the recently planted cotton fields attractive. However, standard cultural practice (e.g., the frequent early season cultivation for weed control, as observed in the Arizona monitoring study), likely already causes significant nest failure or abandonment in these species and thus any incremental risk chlorfenapyr applications might pose would be negligible.

With regard to the late season application, bird usage of Western Cotton at this time appeared to be somewhat higher than earlier in the season, due to the propensity of some species to "follow" the environment created by irrigating the fields. (See Arizona pilot study results). Three points should be kept in mind about this phenomenon. First, the species that frequents fields that have been irrigated is the Red-winged Blackbird. It is the most abundant species by far during the late season and has low site fidelity across the Cotton Belt during the late season. Second, the Red-wing is not a bird of the desert, so its attraction to irrigated fields is not representative of other, desert-adapted species. And third, stomach content analyses of Red-wings in Arizona did not reveal food items that were obviously gleaned from cotton fields. For these reasons, usage of cotton fields by Red-winged Blackbirds in response to irrigation is not necessarily an indication of increased risk for this species, or for other species, late in the use season.

The field study in Louisiana showed that a single application of chlorfenapyr at 0.35 lb. a.i./A had no apparent effects on avian species abundance or diversity. Sensitive telemetry testing showed that there were no differences in survivorship of birds on treated and reference fields. Monitoring results for Section 18 registrations in Southern Cotton, while not highly sensitive, did not find mortality after applications of chlorfenapyr under commercial conditions. There may be some uncertainty as to how well these results from Southern Cotton apply to Western Cotton, but there is no reason to expect the situation in the West to differ radically.

Taken together, the above lines of evidence indicate that use of chlorfenapyr poses low risk to survival of individual birds from late season applications. Incremental risk to survival and reproduction from early season applications is likely low considering standard cultural practices for weed control.

Risk to Local Populations

Risk can be characterized for local populations using Risk Quotients (RQs) -- estimated environmental concentrations (EECs) divided by toxicity measures. This is the standard Tier 1 procedure used by EPA. It must be emphasized that the RQ is not an estimate of actual risk. Rather, in Tier 1 it is used as a screening tool, indicating acceptable safety when not exceeding levels of concern, and highlighting areas where more detailed characterization of exposure and risk are advisable when levels of concern are exceeded. With this general use in mind, we have included RQs for local populations in addition to our qualitative estimates of risk to individual birds.

The RQs for survival and reproduction of local populations were quantitatively estimated from the benchmark laboratory toxicity values, using the Exposure Scenarios developed and presented in the **Analysis** Section. It should be noted that the toxicity value used to calculate chronic RQs is based on a dose that caused no observable effects in laboratory tests.

The RQs in this assessment represent a refinement of standard Tier 1 RQs because they employ measured levels of chlorfenapyr and their decline in avian food items, as well as focal bird species likely to be exposed to chlorfenapyr. Due to the large number of RQ values calculated, the RQs will be summarized here in two tables, one each for Southern and Western Cotton. All RQ values for each scenario in Southern and Western Cotton can be found in Appendix 9.

Using RQs as risk indicators entails significant uncertainties, which will be discussed in more detail in the **Uncertainties** section, below. Briefly stated, the uncertainties include:

- the inherent assumption that the bird is exposed at the level represented by the RQ 100% of the time;
- the unknown degree of comparability among different RQs; and
- the applicability of the RQ to a chronic exposure/risk.

Southern Cotton (Table10)
The qualitative estimates of low to very low risk to survival and reproduction of individual birds in Southern Cotton suggest that risks to local populations would also be low. This assertion is made based on the reasonable deduction that if individuals are not affected, local populations should not be affected.

For the acute oral toxicity in Scenario 1, RQs for the high exposure level (worst-case) exceed EPA's levels of concern by slightly over 2x for the Carolina Wren and the White-eyed Vireo. RQs exceed levels of concern by slightly over 1x for the Northern Cardinal and the Blue Grosbeak. For the moderate exposure level (conservative), the RQs for the Wren and the Vireo exceed levels of concern by about 1x. There are no RQ exceedances at the low exposure level. The results for the most conservative case indicate a potential for effects on four of the seven focal species. However, the RQ implies that any bird would spend 100% of its time on a treated field. This is highly unlikely. The major dietary contributor of chlorfenapyr for all four species that have RQs above the level of concern in this scenario is insects. Recall that biomass of insects on managed fields will be low and this will make it even less likely the level of concern would be exceeded. Considering these modifying factors, the likelihood of exceeding levels of concern is low. In Scenario 2, which allows residues to degrade for 10 days after the last application, all acute oral RQs are below levels of concern for all exposure levels and all species.

For the acute dietary effect in Scenario 1, only the RQs for the high exposure level slightly exceed levels of concern for the Blue Grosbeak and Red-winged Blackbird. RQs are below levels of concern for all other species at the high exposure level. For the moderate and low exposure level, all RQs are below levels of concern. RQs are exceeded for the conservative exposure level that assumes birds forage 100% of their time on treated fields. This is a highly unlikely outcome. When more realistic exposure levels are considered, levels of concern are not exceeded. In Scenario 2, which allows residues to degrade for 10 days after the last application, all acute dietary RQs are below levels of concern for all exposure levels and all species.

As mentioned and emphasized above, in Southern Cotton there will be minimal overlap between late season applications for chlorfenapyr and the breeding season. Therefore, the meaning of chronic RQs is unclear and it is debatable whether chronic RQs should even be calculated. Nonetheless, for completeness, chronic RQs were included.

For Scenario 1, chronic RQs exceed levels of concern for both the high and moderate exposure levels for all species. The levels of concern are exceeded by 7.57x to 19.26x in the high exposure level and by 4.16x to 9.91x in the moderate exposure level. RQs for the low exposure level are below levels of concern for all species. It must be noted that the high exposure level represents a very conservative worst case for two reasons. First, it is unlikely that a bird will forage 100% of the time for many consecutive days on a treated field. Second, the day 0 residues are being compared, without allowance for degradation, to the NOEC for the long term avian reproduction study. Due to the lack of overlap between applications of chlorfenapyr and the breeding season, the low exposure level RQs are most representative of potential exposures. It should also be noted that allowing a short period for residues of chlorfenapyr to degrade reduces the RQs for chronic effects. Thus, in Scenario 2, when residues are assumed to degrade for only 10 days after application, chronic RQs are much lower. Note also that, since the toxicity values used to calculate the chronic RQ is based on a dose that caused <u>no</u> observed effects in a laboratory study, exceeding the acceptable RQ does not necessarily imply adverse effects will occur.

TABLE 10. Overview of Acute and Chronic Risk Quotients, Southern Cotton

Scenario	Type of Effect	RQ Range	EPA Level of Concern	Species with RQs Exceeding the Level of Concern and Their RQs
1 – Late season, time 0 residues	Acute oral	<0.001-1.103	0.5	Carolina Wren – High Exposure Level: 1.062 White-eyed Vireo – High Exposure Level: 1.103 Northern Cardinal – High Exposure Level: 0.513 Blue Grosbeak – High Exposure Level: 0.583 Carolina Wren – Mod. Exposure Level: 0.583 White-eyed Vireo – Mod. Exposure Level: 0.606
	Acute dietary	<0.001-0.852	0.5	Blue Grosbeak – High Exposure Level: 0.798 Red-winged Blackbird – High Exposure Level: 0.852
	Chronic	0.08-19.26	1.0	All 6 Species – High Exposure Level: 7.57 to 19.26 All 6 Species – Moderate Exposure Level: 4.16 to 9.91
2 – Late season, residues after 10 days	Acute oral	0.000-0.105	0.5	None
	Acute dietary	0.000-0.327	0.5	None
	Chronic	0.01-7.38	1.0	Northern Cardinal – High Exposure Level: 2.45 Blue Grosbeak – High Exposure Level: 6.56 Mourning Dove – High Exposure Level: 5.41 Red-winged Blackbird – High Exposure Level: 7.38 Northern Cardinal – Moderate Exposure Level: 1.24 Blue Grosbeak – Moderate Exposure Level: 3.30 Mourning Dove – Moderate Exposure Level: 2.73 Red-winged Blackbird – Moderate Exposure Level: 3.72

Western Cotton (Table 11)

Results for Scenarios 1 and 2 in Western Cotton are exactly the same as those already reported above for Southern Cotton and will not be repeated here.

For the acute oral effect in Scenario 3, RQs for the high exposure level exceed levels of concern for the Carolina Wren and the White-eyed Vireo. In Scenario 4, which allows residues to degrade for 10 days after the last application, all acute oral RQs are below levels of concern for all exposure levels and all species. The results for the worst case indicate a potential for effects on two of the seven focal species. However, it is highly unlikely that any bird would spend 100% of its time on a treated field. The major dietary contributor of chlorfenapyr for both species that have RQs above the level of concern in this scenario is insects. Recall that biomass of insects on managed fields will be very low during the early season and this will make it even less likely the level of concern would be exceeded. Considering these modifying factors, the likelihood of risk is low.

For the acute dietary effect in Scenario 3, RQs are below levels of concern for all exposure levels and for all species. As expected in Scenario 4, which allows residues to degrade for 10 days after the last application, the results were the same.

As mentioned and emphasized above, in Western Cotton there may be overlap between early season applications of chlorfenapyr and the breeding season. For Scenario 3, chronic RQs exceed levels of concern for both the high and moderate exposure levels for all species. The levels of concern are exceeded by 3.25x to 6.79x in the high exposure level and by 1.64x to 3.54x in the moderate exposure level. RQs for the low exposure level are below levels of concern for all species. Again, the high exposure level represents a very conservative worst case for two reasons. First, it is unlikely that a bird will forage 100% of the time for many consecutive days on a treated field. Second, the day 0 residues are being compared, without allowance for degradation, to the NOEC for the long term avian reproduction study. It should also be noted that allowing a short period for residues of chlorfenapyr to degrade reduces the RQs for chronic effects. Thus, in Scenario 4 when residues are assumed to degrade for only 10 days after application, chronic RQs are only slightly above levels of concern for two species, the Blue Grosbeak and the Red-winged Blackbird.

TABLE 11. Overview of Acute and Chronic Risk Quotients, Western Cotton.

Scenario	Type of Effect	RQ Range	EPA Level of Concern	Species with RQs Exceeding the Level of Concern and Their RQs
3 – Early season (mites), time 0 residues	Acute oral	0.000-0.575	0.5	Carolina Wren – High Exposure Level: 0.552 White-eyed Vireo – High Exposure Level: 0.575
	Acute dietary	0.000-0.300	0.5	None
	Chronic	0.03-6.79	1.0	All Species – High Exposure Level: 3.25 to 6.79 All Species – Moderate Exposure Level: 1.64 to 3.54
4 – Early season (mites), residues after 10 days	Acute oral	0.000-0.100	0.5	None
	Acute dietary	0.000-0.100	0.5	None
	Chronic	0.02-2.25	1.0	Blue Grosbeak – High Exposure Level: 2.00 Mourning Dove – High Exposure Level: 1.65 Red-winged Blackbird – High Exposure Level: 2.25 Blue Grosbeak – Moderate Exposure Level: 1.01 Red-winged Blackbird – Moderated Exposure Level: 1.14

In summary, the RQ analysis for local populations generally does not identify acute concerns for exposure levels that are considered to be realistic, i.e., the moderate and low levels. RQs for chronic effects are exceeded for the late season application, but it is not clear what these RQs mean, given that that the toxicity value on which they are based corresponds to an absence of any observed effect and that birds will have largely completed reproduction at the time of late season chlorfenapyr use. RQs for chronic effects from the early season application are within 6.8x of levels of concern in the worst case. In the moderate case, levels of concern are exceeded by 3.5x. When residues were allowed to degrade for only 10 days, RQs exceeded levels of concern by only 2.25X in the worst case. In the low exposure cases, RQs are always less than levels of concern.

Risk to Regional Populations

The risks to the survival and reproduction of regional populations will be semi-quantitatively estimated using several lines of evidence, including the general toxicity of chlorfenapyr to birds, the general partitioning and degradation of chlorfenapyr in the environment, the composition of the borders of the cotton agroenvironment, the percentage of a region treated, and the extent of a region planted to cotton. Each of these lines of evidence will be considered in turn, after a brief discussion of the extent of cotton production and applications for control of the pests on the ALERT® and PIRATE® labels.

Cotton plantings have varied between 7,926,300 and 16,931,400 acres across the Cotton Belt since 1965, see discussion under "Field Borders" in the **Problem Formulation** section (see page 27). The average acreage planted per year for that interval was 12,425,000 acres. Due to the edaphic and climatic requirements of cotton, these values are expected to bracket likely plantings for the foreseeable future. Treatment acreages for the budworm and bollworm, the armyworm complex, and mites were provided in "Ecosystem and Receptor Characteristics – Biotic Factors - Extent and Characteristics of Acreage Planted to Cotton" in the **Analysis** section (page 46). These acreages change from year to year, as might be expected. The annual averages for the period from 1986 to 1996 were 1,103,342 acres for mites, 6,764,362 acres for budworm and budworm, 881,299 acres for beet armyworm, and 378,042 acres for the fall armyworm. Although these treatment acreages are large, they constitute only a small fraction of the nearly 740,000,000 acres of the Cotton Belt.

Southern Cotton

Information on the toxicity and fate and partitioning of chlorfenapyr has been presented above and will not be repeated here.

The composition of the 150 foot borders around of the Southern Cotton agroenvironments was characterized in the definitive GIS study (see page 275 of report assigned MRID. No. 44452607). The primary land cover in the border was other agriculture in 4 of the 9 sites; the percentages of the total area of the border in agriculture ranged from 41 to 67%. Grassland was the predominant land cover in the 150 foot border for 3 of the 9 sites, ranging from 29 to 53% of the border zone acreage. Forest was the predominant land cover in 2 of the 9 sites, ranging from 25 to 40% of the acreage. The next most common land covers in the borders of the Southern Cotton agroenvironments were grassland (4 of 9 sites), other agriculture (2 of 9 sites), and roads, bare ground and forest (1 site each). It can be seen that a high proportion of the acreage in 150 foot border zones is not prime avian habitat.

Even though cotton is produced throughout the area we have termed Southern Cotton, its distribution is patchy. Only 457 of the 1161 counties, or about 39%, produced any cotton. Furthermore the percentage of a county's acreage in cotton was generally low. Of the 457 counties where cotton was grown, 274, or about 60%, had 3% or less of their acreage in cotton. Only two of the 457 counties, or 0.4% had more than 33% of their acreages in cotton (see page 48).

A similar picture emerges when the Southern Cotton region is characterized according to ecoregions. On the average, only 1.83% of an ecoregion was planted to cotton. The percentages planted in cotton ranged from 0.0% (Savannah Ecoregion) to 2.16% (Subtropical Ecoregion).

It becomes apparent that the potential for exposure of regional populations to chlorfenapyr is even lower than the above averages suggest when one considers that not all of the cotton acreage will be treated for the pests on the PIRATE® label, and not all treatments for these pests will be PIRATE. For example, a highly conservative overestimate assumes 19% of the total acres planted to cotton may receive a chlorfenapyr application. This is based on applications to 20% of the acres infested with resistant budworm/bollworm (1.4M acres); 50% infested with mites (0.6M acres) and 50% infested with beet armyworms (0.4M acres).

Western Cotton

The composition of the 150 foot field borders in the Western Cotton agroenvironment was estimated in the definitive GIS study (see page 275 of report assigned MRID. No. 44452607). The primary land cover in the border was other agriculture in 5 of the 6 sites; the percentages of the total area of the border in agriculture ranged from 32 to 67%. Bare ground was the predominant land cover in the 150 foot border for the other site, making up 31% of the border zone acreage. The second most common land covers in the borders of the Western Cotton agroenvironments were roads (2 of 6 sites), bare ground (2 of 6 sites), other agriculture (1 of 6 sites), and grass (1 of 6 sites). Again, it can be seen that a high proportion of the acreage in 150 foot border zones is not prime avian habitat.

Even though cotton is produced throughout the area we have termed Western Cotton, its distribution is patchy. Only 42 of the 138 counties, or about 30%, produced cotton. Furthermore the percentage of a county's acreage in cotton was generally low. Of the 42 counties where cotton was grown, 27, about 64%, had 0 - 3% of their acreage in cotton. Only two of the 42 counties, or about 5%, had greater than 21% of their acreages in cotton.

A similar picture emerges when the Western Cotton region is characterized according to ecoregions. On the average, only 0.78% of an ecoregion was planted to cotton. The percentages ranged from 0.0% (Mediterranean [Mountainous], Temperate Steppe, Temperate Steppe [Mountainous], Tropical/Subtropical Steppe [Mountainous] Ecoregions) to 3.84% (Mediterranean Ecoregion).

As discussed above for Southern Cotton, it becomes apparent that the potential for exposure of regional populations to chlorfenapyr is even lower than the above averages suggest when one considers that not all of the cotton acreage will be treated for the pests on the ALERT® label, and not all treatments for these pests will be ALERT.

Uncertainty Analysis

<u>Risk to Individuals</u>

Southern and Western Cotton
The general toxicological characteristics and the general fate and partitioning of chlorfenapyr in the environment have been established.

The bird species associated with the cotton agroenvironment have been characterized. It is not likely that species which use the cotton agroenvironment during the time that chlorfenapyr will be applied have been missed.

There is no uncertainty as to the times when chlorfenapyr will be applied to cotton; these are dictated by insect management practices in cotton. The information on the relationship between the timing of applications and bird breeding is reliable. There is some uncertainty in the characterization of incremental risk to reproduction when the early season mite applications are made in Western Cotton. At that time the cotton canopy will not be closed and, based on typical cultural practices, the weed food base in the field should be small. Based on observations in the avian censuses and in the avian field study, bird usage of cotton fields during that time is most likely low. Species primarily at risk would be ground-nesters. Existing cultural practices (cultivation for weed control) would be expected to cause significant nest loss. Incremental risks from chlorfenapyr would be negligible. There is also some uncertainty regarding acute risk when the late season worm applications are made in Western Cotton. The uncertainty lies in the degree to which increased usage of irrigated fields by Red-winged Blackbirds is representative of other species. Based on observations in the avian censuses and in the avian field study, usage of cotton fields by most bird species during that time is most likely low.

Unmanaged cotton fields (no crop protection chemical treatments) were shown to be able to carry a smaller biomass of insects per acre than soybeans, which is a crop also grown in cotton producing areas. The biomass of insects in managed cotton fields will be determined by pest management practices and will likely be much lower than the biomass in unmanaged fields. There is some uncertainty in how this will affect bird foraging behavior in the cotton field and the field border. However, it is highly likely that both insect and weed food bases will be higher in the border than in the cotton field and that the cotton agroenvironment is a relatively poor food source compared to nearby areas.

The power and sensitivity of the Louisiana field study for detecting effects, if they were occurring, was high. There is some uncertainty as to the representativeness of the Louisiana results for conditions throughout the Cotton Belt; however, we believe Louisiana conditions are representative of risks in both Southern and Western Cotton.

The sensitivity of the Section 18 monitoring programs was significantly lower than what one could achieve in standard field studies. Nonetheless, the monitoring had the advantage of extensiveness over space. The monitoring programs from several states support the results from the more sensitive Louisiana field study results. Again, there is uncertainty in how well the results represent Western Cotton.

Despite the above uncertainties, it should be recalled that the assessment for individuals is primarily being made using actual measurements from the field. It seems clear that there is less uncertainty associated with using this information in risk characterization than extrapolating from laboratory measures or published residue estimates.

Risk to Local Populations

Southern and Western Cotton

With regard to the Risk Quotient analysis, it should be noted that the uncertainties discussed here exist in all ecological risk assessments relying on RQs.

RQs themselves have uncertainties associated with them. It is not clear what constitutes a significant difference between quotients. Does an RQ of 2.0 necessarily mean more risk than an RQ of 1.0? Does either an RQ of 1.0 or 3.0 prove that there is risk?

Using benchmark toxicity values from laboratory studies assumes that the inherent sensitivity of birds in the wild compares to the sensitivity of the three species tested in the laboratory. This assumption is reasonable since one LD_{50} test and one LC_{50} test were performed with wild-caught birds, and the toxicity profile for chlorfenapyr was quite consistent. This outcome is reasonable, given chlorfenapyr's mode of action.

Focal species and their diets are assumed to be representative of birds in the wild. There was an exhaustive effort to develop accurate diet composition estimates.

The bioavailability of chlorfenapyr in insects, weed seeds, and other substrates in the wild is not known. It was necessary to assume 100% of an ingested residue is bioavailable. However, this may well be an overestimate, based on physical and chemical properties of chlorfenapyr and information from the literature.

It is assumed that the residue levels and degradation patterns observed for chlorfenapyr in Georgia, Louisiana, and Mississippi are representative of conditions in other parts of the Cotton Belt. Residue studies for raw agricultural commodities have shown similar patterns throughout the world, so the assumption is reasonable.

It should be noted that the 1/5 toxicity value benchmark in the standard Risk Quotient calculation is conservative for chlorfenapyr. Chlorfenapyr has a steep dose response curve and 1/5 of the LC_{50} is usually less than the No Observable Effect Level for mortality.

By far the major uncertainty associated with the Risk Quotient approach has to do with the likelihood that birds will receive a toxic dose of chlorfenapyr. Point estimates of residues obscure the temporal, spatial, behavioral and physiological variables that affect the probability of a bird receiving a dose. Field study results show that birds found in cotton agroenvironments are unlikely to ingest significant doses of chlorfenapyr in their diets.

Risk to Regional Populations

Southern and Western Cotton
The classification accuracy for the border habitats in the Geographical Information System was greater than 90%. Thus there is little uncertainty about the composition of the borders of the cotton agroenvironment.

The historical data on cotton acres planted, acreage of counties, acreage of ecoregions and insect infestations are considered adequately accurate and adequately reflective of conditions for the next 20 years (the commercial lifetime of the product). The cotton production data from 1992, used in the county level analysis, represents a year when 13,240,000 acres were planted. This is greater than the overall average of 12,450,000, but less than the 16,931,400 acre maximum and introduces some uncertainty into the risk estimation. At worst, this circumstance suggests that the percentages of counties, states, or ecoregions might be increased by a factor of 1.27 (16,931,400/13,240,000). This would not change the overall conclusion about the extent of cotton and non-cotton acreages.

Risk Description

Individuals

Southern Cotton
Based on a weight-of-the-evidence analysis, the risk that chlorfenapyr will reduce survival or reproduction of individual birds is considered low to very low.

Western Cotton
There is some potential that egg-laying of individual birds could be reduced by early season treatments for mites. This outcome is not likely because bird usage of cotton fields early in the season is likely to be low, due to limited suitability of cotton as a food source.

Because the evidence used included a field study on effects, there is less uncertainty about these qualitative weight-of-evidence estimates than about the quantitative Risk Quotient estimates.
Local Populations

RQs were calculated as one component of the risk characterization for local populations. In general, where RQs exceeded acceptable EPA levels, weight-of-evidence evaluation indicated low likelihood of exposures of concern.

Southern Cotton
For acute oral effects, the RQs exceed EPA levels of concern for the high and moderate exposure levels immediately after application for the Carolina Wren and the White-eyed Vireo. All RQs are below levels of concern in the low exposure case. All RQs are below levels of concern if residues were allowed to degrade for 10 days. For dietary effects, RQs are above levels of concern for the high exposure level for the Blue Grosbeak and the Red-winged

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Blackbird, and are all below levels of concern for all species in the moderate and low exposure levels. All dietary RQs fall below levels of concern when residues were allowed to degrade for 10 days. Recall that RQ exceedances all entail the highly unlikely assumption that birds spend 100% of the time in treated fields.

RQs were calculated for chronic risk even though it was shown that overlap between the late season application and the breeding season is minimal for most species of birds. It is felt that the low exposure level, for which RQs are always less than levels of concern, most accurately represents the potential for chronic exposures and risks. Chronic RQs exceed levels of concern for all species for the high and moderate exposure levels. Allowing degradation of chlorfenapyr residues for 10 days reduces RQs considerably. As we have discussed, the suitability of the RQ as an indicator of chronic risk potential is questionable.

Western Cotton
Conclusions for the acute and chronic risk from the late season application to Western Cotton are the same as those for the late season application to Southern Cotton, above.

Acute oral, dietary, and chronic RQs were calculated for the early season mite application. For acute oral effects, the Risk Quotient analysis exceed EPA levels of concern for the high exposure level immediately after application for the ecological homologs of the Carolina Wren and the White-eyed Vireo. All RQs are below levels of concern for the moderate and low exposure levels, and also if residues were allowed to degrade for 10 days. For dietary effects, RQs are below levels of concern for all exposure levels and all species.

RQs were calculated for chronic risk from the early season mite application. The Risk Quotients for chronic effects exceed levels of concern for the high and moderate exposure levels, but are well below levels of concern for the low exposure level. Allowing degradation of chlorfenapyr residues for 10 days reduces RQs considerably. Chronic RQs exceed levels of concern for the high level of exposure for the Blue Grosbeak, Mourning Dove, and Red-winged Blackbird. Chronic RQs exceed levels of concern for the moderate exposure level for the Blue Grosbeak and the Red-winged Blackbird. As seen above for the late season application, chronic RQs for the low exposure level are well below levels of concern. The issues surrounding use of the RQ as a chronic risk indicator have been described (i.e., use of time zero residue levels and a dose level at which <u>no</u> effects were observed).

<u>Regional Populations</u>

An analysis based on the percentages of counties, states, and ecoregions planted to cotton indicates that there is very low risk to populations in these areas. An analysis of the extent and composition of the borders of cotton agroenvironment shows that much of the border is "Other Agriculture" or "Roads". The proportion of time that birds would spend in areas with potential for significant exposure is very low, and accordingly the risk is also very low.

Interpretation of Ecological Significance: Frequency of Exposure, Extent of Exposure, Importance of Exposed Areas

<u>Individuals</u>

Cotton agroenvironments will be exposed once or twice a year during May through September. Based on historical use-lives of insecticides, the potential for exposure is expected to exist for 20 years. Although an average of 12,425,000 acres of cotton is planted yearly, actual acres treated will average 6,764,362 for budworm and bollworm, 881,299 for the beet armyworm, 378,042 for the fall armyworm, and 1,103,342 for mites. Exposure of the agroenvironment does not imply that birds will encounter or ingest significant residues of chlorfenapyr.

Local Populations

The same frequency and extent information for individuals applies for local populations.

Regional Populations

The same frequency information for individuals and local populations applies for ecoregions. Regarding extent, on the average, only 1.47% of the ecoregions making up the Cotton Belt are planted to cotton. About 11% of this may receive a chlorfenapyr application for control of bollworm and budworm, 4% for beet armyworm, and 5% for mites. The borders of cotton agroenvironments were most often classified as "Other Agriculture", "Bare ground/Urban", and "Roads".

Effectiveness of Label Mitigation Measures

Cyanamid has modified the proposed label for chlorfenapyr use on cotton to mitigate the potential risks that have been identified. We summarize these measures in Table 12.

TABLE 12. Avian Risk Mitigation Measures on the Proposed Chlorfenapyr/Cotton Label

Mitigation Measure	Effects
Restricted Use	Can only be applied by trained, certified applicators
Application Rates and Timing, Pests	
Application rate: Maximum total a.i./A, 0.5 lb.; maximum single application 0.3 lb. a.i./A	Reduces environmental residues in all compartments
Pests limited to beet armyworm, tobacco budworm/bollworm and mites; economic thresholds specified for beet armyworm applications	Limited usage on cotton acreage in any given year; limited potential for residues to carry over from year to year in feed items, soil, or sediment
No more than two consecutive applications	Limited usage on cotton acreage in any given year; limited potential for residues to carry over from year to year in feed items, soil, or sediment
No early season applications (thrips);	Minimize potential for exposures of Western birds that use cotton areas during peak breeding seasons
Early season applications only in the West, and only at low rates	Minimize potential for exposure to breeding birds; limited direct impingement of spray on bare soil
Setbacks and Buffer Zones	
Ground application: 25 ft vegetative strip for fields near water	Reduce drift and resulting residues in field borders and in sediments
Aerial application: 200 ft buffer for fields near water	Reduce drift and resulting residues in field borders and in sediments
Proposed aerial buffers near designated National Wildlife Refuges	No exposure in prime avian habitats

SUMMARY AND CONCLUSIONS

An avian ecological risk assessment was carried out for the use of chlorfenapyr in cotton. The assessment employed the terminology and followed the procedures set out in the United States Environmental Protection Agency's (EPA's) Framework for Ecological Risk Assessment (1992). That is, all components of the Problem Formulation, Analysis, and Risk Characterization phases were carried out.

The valued ecological entity was identified as bird species associated with the cotton agroenvironment. Assessment endpoints were established for: the individual bird and endangered and threatened species, the local (e.g., individual cotton agroenvironment) bird populations, and the regional bird (e.g., county, state, or ecoregion) populations. The assessment endpoints for individual birds and endangered and threatened species were survival and reproduction. For the local population, the assessment endpoint was change in population size due to changes in survival and reproduction. And for the regional population the assessment endpoint was change in population size due to changes in survival and reproduction. For each assessment endpoint, measures of effects, measures of exposure, and measures of ecosystem and receptor characteristics were identified. A generalized conceptual model was provided in narrative and in tabular form.

A refined conceptual model was developed which identified dietary exposure of insectivorous and seed-eating birds as the most significant exposure and risk scenario. In addition, exposures via ingestion of soil and sediment were estimated quantitatively using available information and worst-case assumptions. These estimates are applicable also to earthworm ingestion. (Additional data are currently being gathered on residues in, and populations of, earthworms in cotton fields to validate these exposure estimates for birds that eat worms.) The Cotton Belt was divided into two parts for the purposes of the assessment, based on the key cotton pests and the timing of chlorfenapyr applications. "Western Cotton" and "Southern Cotton" were described with respect to their unique characteristics. Exposure and effects profiles were established and key assumptions of the analysis were discussed.

Risk was estimated for individual birds and endangered threatened species using a weight-of-the-evidence approach employing general information on the toxicity of chlorfenapyr; general information on the partitioning and degradation of chlorfenapyr in the environment; state lists of birds in cotton-growing regions, including habitat preferences; seasonal occurrence; feeding and breeding habits; data from avian censuses; timing of chlorfenapyr usage; and field study results and information about the food base in the cotton agroenvironment. Section 18 monitoring program results were considered as ancillary supporting information. It was concluded that there is a low to very low likelihood for reductions in survival or reproduction of individual birds. The overlap of bird breeding times and applications for mites in Western Cotton presents potential for reductions in egg-laying; however, bird usage of cotton fields during the breeding season is expected to be low due to low food availability. Primarily at risk would be ground-nesting species that use cotton fields; however, incremental risks from chlorfenapyr are negligible when other crop production practices are considered.

Risk was characterized for local populations using refined RQs and a weight-of-the-evidence approach, employing laboratory toxicity test results, measured residue levels in relevant avian food items, and representative bird species likely to be exposed to chlorfenapyr. The calculation of RQs (estimated environmental concentrations divided by toxicity measures) is the standard Tier 1 procedure used by EPA. The RQ is not an estimate of actual risk, but rather, a screening tool. The RQ does not specifically address, or incorporate information relating to, the likelihood that adverse effects will occur. Under highly conservative worst case exposure scenarios, certain RQs exceeded EPA acceptable values, suggesting concern for changes in survival and reproduction. However, the weight-of-evidence, qualitative evaluation indicated that actual risks are likely to be low to very low. Birds will have largely completed reproduction at the time late season applications are made. In Western Cotton where early season applications may be made for mites, low food availability in cotton fields at this time indicates bird usage of cotton, and therefore exposure opportunities, will be low to very low. When more typical exposure cases were used to calculate RQs, resulting values were significantly lower.

Risk was estimated for regional populations using a weight-of-the-evidence approach, employing general information on the toxicity of chlorfenapyr, general information on the partitioning and degradation of chlorfenapyr in the environment, information on cotton borders, historical information on insect infestations, and historical information on cotton planting in counties, states and ecoregions. It was concluded that there is very low likelihood of changing the regional population sizes of county, state, or ecoregion populations. Birds associated with cotton agroenvironment are not tied solely to it; they will use other habitats. Risk is therefore low because of the relatively low proportion of the landscape that is planted to cotton and the limited area within cotton that will be treated.

Mitigation measures on the proposed chlorfenapyr labels for cotton will be effective in further reducing any potential exposures and risks.

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